On page 6, §12 (b) (i), last line: Delete "seven", and insert therefor --eight--;

On page 6, §12 (b) (ii) (B), line 3: Delete "1,020", and insert therefor --929--;

On page 6, §12 (b) (ii) (B), line 3: Delete "five", and insert therefor --six--;

On page 6, last line: Delete "1,021", and insert therefor --1,112--;

On page 6, last line: Delete "two" and insert therefor --three -- and delete "and ten months";

On page 7, §12 (c), line 4: Delete "1,021", and insert therefor –1,112--;

On page 7, §12 (c), line 4: Delete "two" and insert therefor --three -- and delete "and ten months";

On page 7, §12 (e), line 7: Delete "1,021", and insert therefor –1,112--;

On page 7, §12 (e), line 7: Delete "two" and insert therefor --three -- and delete "and ten months";

On page 7, §12 (e), line 7: Delete "4,406", and insert therefor --4,497--;

On page 7, §12 (e), line 8: Delete "one month" and substitute therefor --four months --;

On page 7, §12 (e), last line: Delete "1,021", and insert therefor --1,112--;

On page 7, §12 (e), last line: Delete "two", and insert therefor –three--, and on page 7, §12 (e), last line: Delete "and ten months";

On page 7, §12 (f), last line: Delete "1,021", and insert therefor –1,112--;

On page 7, §12 (g), last line: Delete "June 17, 2011", and insert therefor --Sept 16, 2011--.

REMARKS

In calculating the IND filing-NDA filing/2 period in §12 (b) (ii) (B) of the Application, Applicant incorrectly divided by 2 the entire regulatory review period (IND filing to NDA approval) of 2,041 days instead of the correct IND filing-NDA filing period of 1,859 days, resulting in an answer of 1,020 days instead of the correct 929 days.

This error resulted in the incorrect calculation of the period of extension as 1,021 days instead of the correct 1,112 days.